

U.S. Public Health Service
Bethesda, Maryland 20892

Office of Science Policy
National Institutes of Health
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http://osp.od.nih.gov

October 28, 2016

Name Ph.D., CBSP
Director, Office of Biological and Chemical Safety
Environmental Health and Safety
Washington University
660 South Euclid Avenue
Campus Box 8229
St. Louis, MO 63110

Dear Dr. Name

Thank you for your September 30, 2016, and October 13, 2016, reports to the National Institutes of Health (NIH) Office of Science Policy (OSP) regarding a September 24, 2016, incident in which a graduate student grazed her hand with a needle while administering an antibody to mice infected with Chikungunya virus (CHIKV) in a biosafety level (BL) 3 laboratory at Washington University.

From your report, we understand that the student grazed her finger while handling the needle after performing an injection. She was wearing appropriate personal protective equipment (PPE), including double gloves, at the time of the incident, but the needle broke through both pairs of gloves. She immediately washed her hands with soap and water.

On September 28, 2016, the student developed a fever with severe body aches. On September 29, 2016, she presented with a macular rash which worsened throughout the day. That evening she reported her symptoms and the needle stick to the principal investigator (PI) and went to the hospital. She was kept in hospital overnight for observation, and the following day was seen by an infection disease specialist who sent blood to the state laboratories for CHIKV testing. She was released from hospital that day.

By October 2, 2016, the fever and rash had gone and the student did not develop arthralgia or arthritis, which is often associated with Chikungunya fever. However, she did receive positive CHIKV qPCR results from the Infectious Disease clinic.

In response to this incident, the PI met with all laboratory personnel to discuss the proper reporting of personnel exposures and the processes in place for reporting incidents. The Department of Environmental Health and Safety will add additional slides about sharps safety to the annual laboratory training.

No further information about this incident is required at this time. However, we are concerned that an exposure incident occurred in a BL3 laboratory and went unreported for four days. We recommend that the requirement to immediately report any overt or potential exposure be stressed to all personnel working in high containment. We also recommend evaluating exactly how the injury occurred, including how the

student was handling the needle after conducting the injection. The student may require additional hands on training on how to safely handle sharps. Needles should be discarded in an appropriate sharps container immediately after use to minimize the potential for a stick. The use of safety needles, where the needle can be sheathed immediately after use should also be considered. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at harriskath@od.nih.gov or by telephone at (301) 496-9838 if you have any additional questions.

Sincerely,

Christopher Viggiani, Ph.D.
Program Director, Biosafety and Biosecurity Policy
Biosafety, Biosecurity and Emerging Biotechnology
Policy Division, NIH

cc: Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH
Jessica Tucker, Ph.D., Director, Biosafety, Biosecurity and Emerging Biotechnology Policy Division, NIH
Kathryn Harris, Ph.D., RBP, Senior Outreach and Education Specialist (contractor), Biosafety, Biosecurity and Emerging Biotechnology Policy Division, NIH
Laura Cochran, Program Assistant (contractor), Biosafety, Biosecurity and Emerging Biotechnology Policy Division, NIH

From: [redacted]@wustl.edu>
Sent: Thursday, October 13, 2016 5:17 PM
To: Harris, Kathryn (NIH/OD) [C]
Subject: RE: Report of potential exposure
Attachments: Incident Report Follow Up 161013.pdf

Kathryn,

Attached, please find the completed final report for this exposure. Please let me know if I can provide any additional information.

-Susan

[redacted] PhD, CBSP
Director, Office of Biological & Chemical Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: [redacted]@wustl.edu; Web: ehs.wustl.edu

From: Harris, Kathryn (NIH/OD) [C] [mailto:HarrisKath@mail.nih.gov]
Sent: Friday, October 07, 2016 8:40 AM
To: [redacted]
Subject: RE: Report of potential exposure

Dear [redacted]

Thanks for the update. It would be helpful if you could compile a formal final report regarding the event, immediate actions taken and actions to prevent similar accidents. Our new incident reporting template articulating the kinds of information a report should contain is available at

http://osp.od.nih.gov/sites/default/files/resources/Incident%20Reporting%20Template%20-%202016_2.docx

Thanks,

Kathryn

From: [redacted] [mailto:[redacted]@wustl.edu]
Sent: Friday, October 07, 2016 9:33 AM
To: NIH guidelines <NIHguidelines@od.nih.gov>
Cc: [redacted]@wustl.edu>
Subject: RE: Report of potential exposure

Yesterday afternoon, the PI contacted me to let me know that the student involved has recovered and is back at work. The student never developed arthritis or joint swelling but the PCR results for Chikungunya were positive. Now that the student is recovered, I have asked the PI to talk with her to get more details on the circumstances surrounding the incident and what can be done to prevent similar incidents in the future. I have also stressed the importance of reporting any exposures or potential exposures immediately. I will pass along any additional information as it becomes available but please let me know if there are other items you would like addressed.

[redacted]

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Director, Office of Biological & Chemical Safety
Environmental Health & Safety
Campus Box 8229
Phone: 314-747-0309; Fax: 314-362-6786
Email: [redacted]@wustl.edu; Web: ehs.wustl.edu

From: [redacted]
Sent: Friday, September 30, 2016 6:55 PM
To: NIHGuidelines@od.nih.gov
Cc: [redacted]
Subject: Report of potential exposure

I am writing to report a potential exposure to recombinant DNA. On September 30th, I was contacted by a principal investigator whose graduate student had been admitted to the ER on the night of September 29th with high fever, muscle aches, and rash. On the 30th, the student told the PI that on September 24th she had sustained a scratch with a needle used to inject antibodies into a mouse that had been previously infected with a recombinant clone of Chikungunya virus (la Reunion 2006 strain). The student did not see any blood from the scratch so she did not report it or seek medical attention. The student has not received a diagnosis yet but the Infectious Diseases division of the hospital as well as Occupational and Student Health have been contacted for consultations.

At this time, I do not have any additional details. I am gathering information about the circumstances surrounding the exposure as well as the student's current condition and diagnosis and will pass that information along as soon as I can. The Co-Chairs of the IBC have been notified of this situation and the full committee will discuss the potential exposure at the next scheduled IBC meeting on October 19th.

I will be out of the office for the ABSA conference next week but will be checking email frequently to monitor this situation. I'm also copying [redacted] Associate Biological & Chemical Safety Officer, who will be able to assist you in my absence.

-Susan

[redacted] PhD, CBSP
Biological & Chemical Safety Officer, Washington University
660 South Euclid Avenue, Campus Box 8229
St. Louis, MO 63110
Phone (314) 747-0309; Fax (314) 362-6786
Email: [redacted]@wustl.edu; Web: http://ehs.wustl.edu

Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)



Web: http://osp.od.nih.gov
Address: 6705 Rockledge Dr #750, Bethesda, MD 20817
Phone: (301) 496-9838

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	Washington University in St. Louis
Date of Report:	10/13/16
Reporter name and position:	Name Biological Safety Officer
Telephone number:	314-747-0309
Email address:	Name @wustl.edu
Reporter mailing address:	660 S. Euclid Ave Campus Box 8229 St. Louis, MO 63110
Date of incident:	9/24/16
Name of Principal Investigator:	Name MD, PhD
Is this an NIH-funded project?	YES xNO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☒Personnel exposure ☐Spill ☐Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	x☐YES ☐NO If yes, date of approval: Renewed 8/29/16
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☒BL3 ☐BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-1-b, III-D-4-a
Has a report of this incident been made to other agencies? If so, please indicate	☐CDC ☐USDA ☐FDA ☐EPA ☐OSHA ☐Funding agency/sponsor ☐State or local Public Health ☐Law enforcement ☐Other (please describe):
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Chikungunya virus (recombinant strain: LR OPY2006)

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

A description of:

- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space)

- Who was involved in the incident/violation, including others present at the incident location?

  Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)

- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event

- The training received by the individual(s) involved and the date(s) the training was conducted

- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation

- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation

- The personal protective equipment in use at the time of the incident/violation

- The occupational health requirements for laboratory personnel involved in the research

- Any medical surveillance provided or recommended after the incident

- Any injury or illness associated with the incident

- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)

The incident took place in our ABSL3 laboratory space (inside a biosafety cabinet) on Saturday 9/24/16. A graduate student was administering antibody to mice infected with CHIKV-LR2006 strain via an intraperitoneal route at a time point where infectious virus would still be present in the mice. There were no other lab members present at the time, and proper BSL3 personal protective equipment was in use at the time of the incident (double gowns, double gloves, double shoe covers, hair net, and face mask). All lab personnel that use the BSL3 space have had proper training in accordance with national and institutional guidelines.

She grazed a finger on her left hand while handling the needle after an IP injection. The needle did break through both sets of gloves (by visible inspection), but there was no visible sign of blood (i.e. it didn't seem like a deep needle stick). The student washed her hands with soap and water immediately following the needle stick.

Wednesday evening (9/28/16 - 4 days post needle stick) the graduate student started running a fever and had severe body aches and chills. Thursday morning (9/29/16) she presented with a macular rash, which progressively worsened throughout the day. Thursday evening she reported her symptoms and needle stick incident to her PI and checked into the ER for treatment. She was kept overnight for observation and was given ibuprofen for the fever and pain and fluids for hydration. On Friday 9/30/16 she was seen by the Infectious Disease consult service and blood was sent to the state labs for CHIKV tests. She was released from the hospital that Friday afternoon.

By Sunday (10/2/16) her rash and fever were gone, and she was back at work on Tuesday 10/4/16. Ultimately, she experienced only 3 days of more severe symptoms, and she never developed the arthralgia and arthritis often associated with chikungunya fever. On Thursday 10/6/16 she did receive positive CHIKV qPCR results from the Infectious Disease clinic.

Has the IBC reviewed this incident?	xYES ☐NO
Please describe the root cause of this incident:	Accident

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

Prior to this incident, EH&S distributed a sharps safety reminder through the University's Research News tool. The day prior to the incident, EH&S sent annual safety and compliance reports to all department chairs and business managers in departments that have laboratories and clinics. The report highlighted needle stick trends, asking departments to focus on reducing needle sticks and other common injuries, and asked department chairs to pay special attention to prompt reporting of any potential exposure to recombinant DNA-containing material, as required by NIH. Following this incident, the PI discussed proper reporting of personnel exposure in a lab meeting with all members of the lab and procedures in place for reporting such incidents were reviewed with all members of the lab being present. EH&S will also add additional slides about sharps safety to the annual laboratory safety training. The IBC will discuss at the October meeting what other educational steps can be taken to minimize the chance of sharps injuries in the future.

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**

- **Submitting this completed template to NIH OSP does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.**

Harris, Kathryn (NIH/OD) [C]

From: Name @wustl.edu>
Sent: Friday, October 07, 2016 9:33 AM
To: NIH guidelines
Cc: Name
Subject: RE: Report of potential exposure

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Name

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Email: Name @wustl.edu; Web: http://ehs.wustl.edu

Harris, Kathryn (NIH/OD) [C]

From:	[redacted]@wustl.edu>
Sent:	Friday, September 30, 2016 7:55 PM
To:	NIH guidelines
Cc:	[redacted]
Subject:	Report of potential exposure

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